EUROPEAN
COMMISSION

Brussels, 10.3.2021
C(2021)1726 (final)

COMMISSION IMPLEMENTING DECISION

of 10.3.2021

correcting Decision C(2020)8457 final of 25.11.2020 amending the marketing authorisation granted by Decision C(2018)5718 final for "Yescarta - axicabtagene ciloleucel", an orphan medicinal product for human use

(Text with EEA relevance)

(ONLY THE DUTCH TEXT IS AUT HENTIC)

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THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[1] ,

Having regard to Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products[2], and in particular Article 17(2) thereof,

Having regard to the changes to the terms of the decision granting the marketing authorisation requested by Kite Pharma EU B.V. in accordance with Regulation (EC) No 1234/2008,

Having regard to the opinion of the European Medicines Agency, formulated on 28 May 2020 by the Committee for Medicinal Products for Human Use,

Whereas:

(1) The Commission has been made aware that the Product Information (PI) of Decision C(2020)8457 final of 25.11.2020 requires linguistic amendments.

(2) This Decision rectifies Decision C(2020)8457 final by correcting the relevant Annexes I, II and III accordingly. It should apply retroactively from the date of notification of that Decision.

HAS ADOPTED THIS DECISION:

Article 1

Decision C(2020)8457 final is corrected as follows:

[1] OJ L 136, 30.4.2004, p. 1.
[2] OJ L 334, 12.12.2008, p. 7.

Annexes I, II and III shall be replaced by the text set out in Annexes I, II and III to this Decision.

Article 2

This Decision applies from 26 November 2020.

Article 3

This Decision is addressed to Kite Pharma EU B.V., Tufsteen 1, 2132 NT Hoofddorp, Nederland.

Done at Brussels, 10.3.2021

For the Commission

Sandra GALLINA
Director-General